

**QUANTITY:** 5 devices at Toledo, Ohio.

**SHIPPED:** Between 11-25-57 and 1-23-58, from Adamsville, Pa.

**RESULTS OF INVESTIGATION:** The home unit was composed of a kit consisting of a Thermo-Cyclopad with a motor having Cyclo-Massage action, contained in a heating pad of foam rubber which held a heating coil, with a control box; also a hand massage unit with a control box.

**LIBELED:** 3-21-58, N. Dist. Ohio.

**CHARGE:** 502(f)(1)—the labeling of the article, while held for sale, failed to bear adequate directions for use in the treatment of polio, polyneuritis, paralytic stroke, paralysis caused by spinal injury, prevention of ulcerated teeth, prevention and treatment of colds and sinus trouble, treatment of muscular dystrophy, multiple sclerosis, crippling arthritis, baldness, stomach ulcers, and influenza, which were the diseases and conditions for which the device was offered in oral advertising at Toledo, Ohio, on February 12, 1958, by Mrs. Ruth Mitchell, a saleswoman for General Home Service, Inc., trading as Niagara of Toledo.

**DISPOSITION:** 5-26-58. Default—delivered to Food and Drug Administration.

### **DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH**

#### **5718. Vegetable oils. (Inj. No. 312.)**

**COMPLAINT FOR INJUNCTION FILED:** 5-14-57, S. Dist. Calif., against Strathmore Oils & Fats Co., Inc., Strathmore, Calif., Malaga Oil Products Div. of Leghorn Trading Co., Inc., Lindsay, Calif., Georges Valabregue, president and general manager of Strathmore, and James B. Fowler, vice-president and general manager of the Lindsay plant of Malaga. Amended complaint filed 9-7-57.

**CHARGE:** The original complaint alleged that the defendants were engaged in the business of manufacturing, preparing, and distributing oils for edible and medicinal purposes; and, that the defendants had been and were, at the time of filing the complaint, introducing and causing to be introduced, and delivering and causing to be delivered for introduction into interstate commerce, said oils which were adulterated within the meaning of 501(a)(1) and 501(a)(2).

The complaint alleged also that the oils were adulterated under the provisions of the law applicable to foods, as reported in notices of judgment on foods, No. 24741.

The original complaint alleged that the raw materials involved, namely, olive pomace, sesame seed, walnut oil stock, almond oil stock, and other by-product materials, were purchased from various food processors for use in the manufacture of the oils and were delivered to the Strathmore plant of defendant, Strathmore Oils & Fats Co., Inc.; that, upon receipt, the raw materials were stored under insanitary conditions at the Strathmore plant; that the contaminated raw materials were subsequently dried and put through a solvent extraction process to remove the oils in such raw materials; that the oils so extracted were placed in storage tanks at the Strathmore plant and held there until they were delivered to the Lindsay plant of the Malaga Oil Products Division; and, that upon delivery to the Lindsay plant, the oils were subjected to a refining process after which they were shipped in interstate commerce.

For a description of the insanitary conditions at the Strathmore plant, see the above-mentioned notice of judgment on foods, No. 24741.

The amended complaint alleged that the olive pomace was purchased by Strathmore from olive pressors and consisted of the residue remaining after olive oil was pressed from olives; that the olive pomace was handled as garbage by the olive pressors and exposed to the elements and to insects, birds, rodents, and squirrels; and, that the olive pomace was adulterated when it reached Strathmore by reason of such exposure.

DISPOSITION: On 5-14-57, the court issued a temporary restraining order restraining the defendants from shipping or causing the shipment in interstate commerce, and, more particularly, from delivering or causing the delivery to persons in California known to be engaged in the distribution of oils in interstate commerce, oils which consisted in part of filthy substances or had been prepared or held under insanitary conditions.

On 10-29-57, the cause came on for a hearing on the motion for a preliminary injunction. Thereafter, on 11-6-57, the court orally denied the motion.

Subsequently, on 2-11-58, the Government filed a motion to dismiss the complaint, based upon the grounds that (1) there had been a material improvement in the operations of Strathmore Oils & Fats Co., Inc., especially in the handling of raw materials and extracted oils; (2) that the temporary restraining order had resulted in the adoption by the defendants of a sanitation program encompassing the suppliers of raw materials; and (3) that there appeared to be no further need for an injunction to prevent violation of the Act. The motion to dismiss was granted by the court on 2-12-58.

#### DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS\*

**5719. Chorionic gonadotropin.** (F.D.C. No. 41317. S. No. 68-044 M.)

QUANTITY: 180 vials at Kansas City, Mo.

SHIPPED: 4-25-57, from Los Angeles, Calif.

LIBELED: 1-6-58, W. Dist. Mo.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it was represented to possess, namely, 10,000 I.U. of *chorionic gonadotropin* potency per vial; and 502(a)—the label statement "10,000 Int. Units Chorionic Gonadotropin" was false and misleading as applied to a product, the potency of which was substantially less than 10,000 I.U. of *chorionic gonadotropin*.

DISPOSITION: 2-25-58. Default—destruction.

**5720. Chorionic gonadotropin.** F.D.C. No. 41358. S. No. 86-963 M.)

QUANTITY: 969 vials at Kansas City, Mo.

SHIPPED: 9-26-57 and 10-16-57, from Orange, N.J.

RESULTS OF INVESTIGATION: Examination showed that the article contained substantially less than 2,500 I.U. of *chorionic gonadotropin* potency per vial.

LIBELED: On or about 1-16-58, W. Dist. Mo.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it was represented to possess, namely, 2,500 I.U. of *chorionic gonadotropin* potency per vial.

\*See also Nos. 5706, 5708, 5711, 5716.